

Lot: 0120420

Hubel Gedian Humanwell Pharmaceutical Co., Ltd.

Address: Gedian Economic Development District, E-zhou 436070, Hubei, P. R. China



CERTIFICATE OF ANALYSIS

Product : Finasteride Micronized (Form I)

Quantity : 20kg

Mfg. date : 2019.12.03

Batch No. : FTD191201

Specification: EP9

Expiry date: 2024.12.02

Item	Specifications	Results
Description	White or almost white crystalline powder	Almost white crystalline powder
Identification	IR:Comparison:finasteride CRS.	Sample spectrum is similar to that of reference standard.
Loss on drying	$\leq 0.5\%$	0.09%
Specific optical rotation	$+12.0^{\circ} \sim +14.0^{\circ}$ (on dried substance)	$+12.9^{\circ}$
Related substances	Impurity A $\leq 0.3\%$	0.07%
	Impurity C $\leq 0.3\%$	0.13%
	Any other unknown impurity $\leq 0.10\%$	0.05%
	Total impurities $\leq 0.5\%$	0.30%
Residual Solvents	Methanol ≤ 3000 ppm	134ppm
	Ethanol ≤ 5000 ppm	340ppm
	Methylene chloride ≤ 600 ppm	Not detected
	Isopropyl acetate ≤ 5000 ppm	22ppm
	Toluene ≤ 890 ppm	Not detected
Assay	98.0 ~ 102.0 % (on dried substance)	100.6%
Particle Size	100% < 20 μ m	Conform

Conclusion: Complies with the requirements of EP9

Q.C. director:

Date: 2020.03.12

QP:

Date: 2020.03.12